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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,421	09/01/2006	Nobuhiko Fushimi	Q96479	3051
23373 7590 12/10/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
HENRY, MICHAEL C				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
12/10/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/591,421

Applicant(s)

FUSHIMI ET AL.

Examiner

MICHAEL C. HENRY

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/21/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-22, 27-31 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-18, 27, 28 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/21/10.

The amendment filed 09/21/10 affects the application 10/591,421 as follows:

1. Claims 1-11, 15, 17, 18, 27, 28 and 35 have been amended. Claim 14 has been canceled. Claims 1-13, 15-18, 27, 28 and 35, the invention of Group I is prosecuted by the examiner. Claims are 19-22, 29-31 are withdrawn. Applicants' amendments have and arguments have overcome the rejections of prior office action mailed 03/22/10, except for the rejection made under 35 U.S.C. 112, second paragraph. However, a new grounds rejection is set forth herein below.
2. The responsive is contained herein below.

Claims 1-13, 15-22, 27-31 and 35 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-18, 27, 28 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a fused heterocyclic derivative represented by a general formula (I). However, the claim is indefinite since the symbols or letters A¹ and A² in the said general formula (I) are not defined in the claim. Consequently, the identity and the metes and bounds of said derivative that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 7, 9-13, 15, 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Rybczynski et al. (WO 2005012318 A2).

Claim 1 is drawn to a fused heterocyclic derivative represented by a given general formula (I). Rybczynski et al. disclose Applicant's fused heterocyclic derivative or compound (see abstract and claims; see also entire reference). Rybczynski et al.'s compound is named D-Glucitol, 1,5-anhydro-1-C-[3-[(4-ethylphenyl)methyl]-1H-indol-5-yl]-, (1S)- and has a Cas # = 840541-25-5 (see abstract and claims; see also entire reference). Claims 2, 4, 7, 9-13, 15 and 16 are also anticipated by Rybczynski et al. (see abstract, compound with Cas # = 840541-25-5; see also claims and entire reference). It should be noted that Rybczynski et al.'s compound or composition is the same as applicant's compound or composition and should inherently have the same effect or property of being an SGLT inhibitor. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for inhibition of postprandial hyperglycemia or for the treatment of diabetes, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Also, it should be noted that Rybczynski et al. disclose that their compound or composition is an SGLT inhibitor (see claims and entire reference). In addition, Claims 1-3, 7, 9-13, 15, 16, 27, 28 are anticipated by Rybczynski et al. since Rybczynski et al. disclose

Applicant's fused heterocyclic derivative or compound named, D-Glucitol, 1,5-anhydro-1-C-[3-[2-(4-methoxyphenyl)ethyl]-1H-indol-5-yl]-, (1S)- and has a Cas# = 840541-37-9 (see abstract and claims; see also entire reference). It should be noted that Rybczynski et al.'s compound or composition is the same as applicant's compound or composition and should inherently have the same effect or property of being an SGLT inhibitor. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for inhibition of postprandial hyperglycemia or for the treatment of diabetes, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Also, it should be noted that Rybczynski et al. disclose that their compound or composition is an SGLT inhibitor (see claims and entire reference).

It should be noted that applicant's claimed to foreign priority over Japan 61428/2004 (03/04/2004) has not over been perfected, since an English translation of the said foreign priority document is not filed. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP j 201. 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 18, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rybczynski et al. (WO 2005012318 A2).

Claim 1 is drawn to a fused heterocyclic derivative represented by a given general formula (I). Claim 17 is drawn to the pharmaceutical composition as claimed in claim 10, which is a sustained release formulation. Claim 18 is drawn to the human SGLT inhibitor as claimed in claim 11, which is a sustained release formulation. Claims 27 and 28 are drawn to composition comprising a combination of said compound and selected compound or substance.

Rybczynski et al. disclose Applicant's fused heterocyclic derivative or compound (see abstract and claims; see also entire reference). Rybczynski et al.'s compound is named D-Glucitol, 1,5-anhydro-1-C-[3-[(4-ethylphenyl)methyl]-1H-indol-5-yl]-, (1S)- and has a Cas # = 840541-25-5 (see abstract and claims; see also entire reference). Also, Rybczynski et al. disclose Applicant's fused heterocyclic derivative or compound named, D-Glucitol, 1,5-anhydro-1-C-[3-[2-(4-methoxyphenyl)ethyl]-1H-indol-5-yl]-, (1S)- and has a Cas# = 840541-37-9 (see abstract and claims; see also entire reference). It should be noted that Rybczynski et al.'s compound or composition is the same as applicant's compound or composition and should inherently have the same effect or property of being an SGLT inhibitor. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for inhibition of postprandial hyperglycemia or for the treatment of diabetes, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Rybczynski et al. disclose that their compounds can be used to treat diseases or conditions including diabetes, syndrome X and obesity (see abstract and claims).

The difference between Applicants' claimed compound or composition and Rybczynski et al.'s compound or composition is that Rybczynski et al. do not explicitly disclose a sustained release formulation, per se. However, Rybczynski et al. disclose that their formulation can be administered in different form including tablets, pills, capsules, granules, suspensions and solutions and can be administered by different routes including oral, intravenous, subcutaneous and parenteral. This implies that different formulations of Rybczynski et al.'s compound including sustained release formulation can be used or administered as needed. Furthermore, the use of different formulation of active ingredients such as Rybczynski et al.'s compound is common in the art and is well within the purview of a skilled artisan.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare different formulation of Rybczynski et al.'s compound such as sustained release formulation, based on factors such as the type and/or severity of the condition or disease and the type, age and weight of the patient.

One having ordinary skill in the art would have been motivated to prepare to prepare different formulation of Rybczynski et al.'s compound such as sustained release formulation, based on factors such as the type and/or severity of the condition or disease and the type, age and weight of the patient. It should also be noted that the use of different formulation of active ingredients such as Rybczynski et al.'s compound is common in the art and is well within the purview of a skilled artisan.

Response to Arguments

Applicant's arguments with respect to rejection made under 35 U.S.C. 112, second paragraph with respect to claims 1-11, 15-18, 27, 28 and 35 have been considered but are not found convincing.

The applicant argues that the claim is not indefinite. However, the claim is indefinite since the symbols or letters A¹ and A² in the said general formula (I) are not defined in the claim. Consequently, the identity and the metes and bounds of said derivative that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Applicant's arguments with respect to claims 1-11, 15-18, 27, 28 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
December 5, 2010.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623